

LARRY M. KJELDGAARD, DO

Orthopedic Surgeon

1305 Airport Freeway • Suite 302 • Bedford, TX 76021  
Phone (817) 571-9099 • Metro (817) 540-1982 • Fax (817) 571-5282

12 21 '99 DEC 14 P1 58

December 2, 1999

Document Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket Number 97N-484S**

To Whom It May Concern:

My name is Larry M. Kjeldgaard, D.O. I am an orthopedic surgeon who concentrates in spine surgery. I am practicing in Bedford, Texas and deal mainly with surgical patients regarding cervical; thoracic, and lumbar spine problems.

It has come to my attention about a proposal for the Food and Drug Administration to regulate allograft tissue. I am very concerned about the new regulations the FDA may attempt to put into effect in regards to "safety" would curtail the supply of bone products which I rely on for treating surgical spine patients. I find the current rules and regulations in place to be quite satisfactory and I am convinced that the sterility and safety of tissues in question is quite well maintained, and I do not feel additional regulation is warranted or needed on the companies involved with allograft of bone tissue. I would implore you not to pass additional regulations or rules on the use of allograft bone tissue. I feel the marketplace is taking care of that problem quite well, and again, I am convinced of the sterility and the safety of these tissues that I am using to treat my patients.

Thank you for your attention to this matter.

Sincerely,



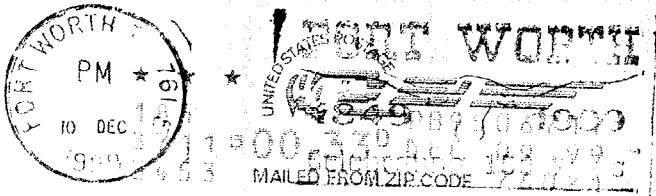
Larry M. Kjeldgaard, D.O.  
Orthopedic Surgeon

cc WC  
Ron Pickard, Medtronic Sofamore Dynek, 1800 Pyramid Place, Memphis, Tennessee 38132

97N-484S

C115

RICHARD F. HAENKE, D.O.  
305 AIRPORT FREEWAY, STE 302  
BEDFORD, TX 76021



DOCUMENT MANAGEMENT BRANCH  
HFA-305  
FOOD & DRUG ADMINISTRATION  
5630 FISHERS LANE, ROOM 1061  
ROCKVILLE, M.D. 20852

208570001

